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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/029,551 | 12/20/2001 | Indu Parikh | WAPH.002.04US | 6080 |
| 31272 | 7590 | 12/01/2004 | EXAMINER | |
| RAE-VENTER LAW GROUP, P.C. P.O. BOX 1898 MONTEREY, CA 93942-1898 | | | GALVEZ, JAMES JASON | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1647 | |

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/029,551 | Applicant(s) PARIKH ET AL. | |
| | Examiner J. Jason Galvez | Art Unit 1647 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 19-24, 28-34 and 38-44 is/are pending in the application.
- 4a) Of the above claim(s) 1-3, 19-24, 28-29, 34 and 39-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-33, 38 and 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>3/08/02 & 12/17/02</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group IV in the reply filed on 4/26/2004 is
5 acknowledged. The traversal is on the ground(s) that searching the inventions together,
especially IV and I/III would not impose an undue burden on the Examiner and USPTO
resources. Applicant asserts that the products of Group IV are used in the method of
Group I and III. The argument to search the inventions together are not found
persuasive because the products of Group IV and the methods of both Group I and III
10 would constitute a different search, as evidenced by Applicant's admission that the four
inventions are independent and distinct and by separate classification of the inventions.

The requirement is still deemed proper and is therefore made FINAL.

In regards to Applicant's response filed on 9/17/2004. Applicant has elected
without traverse the species Gastrin and EGF 1-53.

15 Newly submitted claims 39-43 are directed to an invention that is independent or
distinct from the invention originally claimed for the following reasons: they are directed
to methods, while the elected invention is directed to products, thus the inventions are
classified separately. Furthermore the inventions are directed to methods of treating
diabetes and methods of expanding population of insulin secreting cells, a search of
20 witch, would not be coextensive with the elected invention. Accordingly, claims 39-43
are withdrawn from consideration as being directed to a non-elected invention. See 37
CFR 1.142(b) and MPEP § 821.03.

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As of 9/17/2004, claims 4-18, 25-27, and 35-37 have been cancelled. Pending claims are 1-3, 19-24, 28-34, and 38-44. Claims under examination are claims 30-33, 38, and 44.

5

Specification

The disclosure is objected to because of the following informalities: in the first paragraph of the specification Applicant has not disclosed the US Patent # that corresponds to the priority claim of application 07/992,255.

Appropriate correction is required.

10

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15

Claim 30-33, 38, and 44 are indefinite because a kit, by definition, must contain 2 or more elements and the interrelationships between the elements must be explicitly stated (see *In re Venezia* 530 F.2d 956 CCPA 1975). In the instant case, the relationship between the components, gastrin/CCK receptor ligand and EGF receptor ligand, is not specified. Furthermore, the specification does not provide a standard for ascertaining the requisite degree of the number of components and the ratio of components. Therefore, a person of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

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Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is drawn to a kit comprising a gastrin/CCK receptor ligand and an EGF receptor ligand claimed as "single dosages". Dosages are

5 described in the specification as ranging from pico grams per kilogram to milligrams per kilogram, which does not adequately limit the "single dosage"(p. 12: lines 31-32). It is unclear to the Examiner what constitutes "single dosages" based on the broad nature of the claim, dosage range spans from 1 to a billion (10^{-3} to 10^{-12} per kilogram body weight). The dosage range recited does not adequately limit "single dosage", making

10 the claim indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

15 A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20 Claims 30-33, 38, and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Conteas et al. (Proc Soc Exp Biol Med. 1987, Vol. 184(3): pp. 307-311). Conteas et al. teach a simultaneous administration of both gastrin and EGF (p. 309: Figure 2 and Table II). The recitation of a "kit" does not change the nature of the instant invention; it only amounts to an intended use. The invention claimed is not patentably

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distinct from the composition disclosed by Conteas et al. Thus, Conteas et al. meet the limitation of the claims.

Double Patenting

5 Claims 30-33 and 38 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,288,301. Although the conflicting claims are not identical, they are not patentably distinct from each other because both comprise compositions comprising a gastrin/CCK receptor ligand and an EGF receptor ligand. The instant invention recites the
10 composition as a kit and patent '301 recites the composition as a pharmaceutical. Although, there are differences between a "kit" and a "pharmaceutical" regarding such issues as intended use and degree of purity they are not patentably distinct. Having either a "kit" or a "pharmaceutical" would make it obvious to have the other.

 Claims 30-33 and 38 are provisionally rejected under the judicially created
15 doctrine of double patenting over claims 48, 50-51, and 53-71 of copending Application No. 10/691,123. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

 The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that
20 copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: compositions containing a gastrin/CCK receptor ligand and an EGF receptor ligand.

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Claims 30-33 and 38 are provisionally rejected under the judicially created doctrine of double patenting over claims 59-60, 63, and 72 of copending Application No. 10/457,126. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

5 The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: compositions containing a gastrin/CCK receptor ligand and an EGF receptor ligand.

10

Conclusion

NO CLAIMS ARE ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **J. Jason Galvez, Ph.D.** whose telephone number is 15 **571-272-2935**. The examiner can normally be reached Monday through Friday 9 AM to 5 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback, Ph.D.** can be reached at **571-272-0887**.

The fax phone number for the organization where this application or proceeding is assigned is **703-872-9306**. Information regarding the status of an application may be 20 obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through


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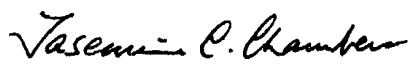
Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

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JJG
11/18/2004


JANET ANDRES
PRIMARY EXAMINER


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